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| APPLICATION NO.                | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--------------------------------|-------------|----------------------|-------------------------|------------------|
| 09/685,828                     | 10/10/2000  | Elliott S. Klein     | 17171CIP4DIV            | 4591             |
| 7590 01/14/2004                |             |                      | EXAMINER                |                  |
| Carlos A Fisher T2 7H          |             |                      | HILL, MYRON G           |                  |
| Allergan Inc 2525 Dupont Drive |             |                      | ART UNIT                | PAPER NUMBER     |
| Irvine, CA 92612               |             |                      | 1648                    | 10               |
| ,                              |             |                      | DATE MAILED: 01/14/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| •  |  | Application No.  | Applicant(s)   |  |  |  |
|--|--|--|--|--|--|--|
|  |  | 09/685,828   | KLEIN ET AL.   |  |  |  |
|  | Office Action Summary  | Examiner   | Art Unit   |  |  |  |
|  |  | Myron G. Hill  | 1648   |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |  |  |  |  |
| THE I - External form of the control | ORTENED STATUTORY PERIOD FOR REPL' MAILING DATE OF THIS COMMUNICATION. msions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period or re to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).  | 36(a). In no event, however, may a reply be tin<br>y within the statutory minimum of thirty (30) day<br>will apply and will expire SIX (6) MONTHS from<br>, cause the application to become ABANDONE   | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).   |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 22 O   | <u>ctober 2002</u> .   |  |  |  |  |
| 2a) <b>X</b>   | This action is <b>FINAL</b> . 2b) This   | action is non-final.   |  |  |  |  |
| 3)□  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |  |  |  |  |
| Dispositi  | ion of Claims  |  |  |  |  |  |
| 4)🖂  | I)⊠ Claim(s) <u>21- 41</u> is/are pending in the application.  |  |  |  |  |  |
|  | 4a) Of the above claim(s) 26-32, 34, 36-38, 40, and 41 is/are withdrawn from consideration.  |  |  |  |  |  |
| 5)   | Claim(s) is/are allowed.   |  |  |  |  |  |
| 6)□  | Claim(s) <u>21- 25, 33, 35, and 39</u> is/are rejected.  |  |  |  |  |  |
| •  | Claim(s) is/are objected to.   |  |  |  |  |  |
| 8)[_]  | Claim(s) are subject to restriction and/o  | r election requirement.  |  |  |  |  |
| Applicat   | ion Papers   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |  |  |  |  |  |  |
| 10)[   | ☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |  |  |  |  |
|  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |  |  |  |
| _  | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |  |  |  |  |  |  |
| * 5<br>13)   | Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureau See the attached detailed Office action for a list Acknowledgment is made of a claim for domestifice a specific reference was included in the first 7 CFR 1.78.  1) The translation of the foreign language production of the foreign language production of the foreign language production of the first sentence of the foreign was included in the first sentence of the foreign language production. | s have been received. s have been received in Application rity documents have been received in Application (PCT Rule 17.2(a)). of the certified copies not received priority under 35 U.S.C. § 119(ast sentence of the specification of the covisional application has been received priority under 35 U.S.C. §§ 120 | ion No  ed in this National Stage  ed.  e) (to a provisional application)  r in an Application Data Sheet.  eeived.  and/or 121 since a specific |  |  |  |
| Attachmen  | e of References Cited (PTO-892)  | 4) T Interview Summary   | (PTO-413) Paper No(s)  |  |  |  |
| 2) Notic   | te of References Cited (PTO-692) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) _  | 5) Notice of Informal F  | Patent Application (PTO-152)   |  |  |  |

Application/Control Number: 09/685,828

Art Unit: 1648

#### **DETAILED ACTION**

This action is in response to Reconsideration and Terminal Disclaimer filed 17 October 2002.

Claims under examination are 21- 25, 33, and 39 with the elected species of retinoid receptor.

## Rejections Withdrawn

## Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21- 25, 33, and 39 were rejected under 35 U.S.C. 102(a) as being anticipated by Klein (1996 J Bio Chem from IDS).

The reference is not prior art and the rejection is withdrawn.

Claims 21- 25, 33, and 39 were rejected under 35 U.S.C. 103(a) as being obvious over Klein (US 5776699).

The reference is not prior art and the rejection is withdrawn.

### **Double Patenting**

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Claims 21- 25, 33, and 39 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3- 5, and 14- 20 of U.S. Patent No. 5776699.

Applicant has filed a terminal disclaimer and has overcome the rejection.

#### Rejections Maintained

### Claim Rejections - 35 USC § 112

Claims 21- 25, 33, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if the agonist in claim 21 a) line 1 is the ligand recited in b) line 4. The method of claim 21 is not clear. Is the first part of part "b" a recap of part "a"? There is a comparison part "b" in the claim; however, since all unknown compounds are not going to be inverse agonists, it is not clear what result of the comparison is needed to determine and conclude that the compound is a inverse agonist. In other words, it is not clear if the method results in the determining whether a compound is an inverse agonist as a conclusion and what result indicates that determination.

Applicant argues that it is any ligand, the expression of reporter gene is measured in absence of any ligand and the effect is measured, and that the language is clear to one of ordinary skill in the art in light of the specification.

Applicant's arguments have been fully considered and not found persuasive.

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Page 16, lines 15- 30, defines negative hormone (also called inverse agonist).

This passage discloses that only a subset of antagonists will be negative hormones and that these compounds are ligands. Example 12, for example, discloses an assay to determine negative hormones.

It is clear from the specification that the test compounds must be antagonists and must be ligands. Therefore the reference to "ligand" must differentiate between test compound and agonist.

The step recited in b) is not clear. Part b) comprises detecting repression of the ability of said polypeptide to stimulate expression. There is no conclusion that indicates that the result/comparison is what determines the negative hormone and that is the result. It would be more clear if the step were rewritten to be contacting polypeptide without "ligand," and adding a step of comparing the levels wherein (comparative factor) the compound is a negative hormone.

The rejection is maintained.



No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron 6. Hill Patent Examiner January 8, 2004

JEFFREY STUCKER
PRIMARY EXAMINER